

## ENZYMATIC THERADY CHRPTCRATEC

NF Formulas a PhytoPharmica

Tyler Encapsulations - Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 - -P: 503.582.8386 F: 5037582.8467

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920,469.1313 . . . . E: 888.570.6460 (Enzymatic) P(920,489.9099 • 7F: 920.469.4418 (Phyto)

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What Better feels like."

March 25, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Female Balance™	Essential vimtains and minerals that are depleted in women who experience premenstrual syndrome (PMS).*	Vitamin A (as beta carotene), Vitamin C (as ascorbic acid), Vitamin E (as d-alpha tocopheryl acid succinate), Thiamin (as thiamin HCL) (vitamin B1), Riboflavin (vitamin B2), Folic Acid, Vitamin B6 (as pyridoxide HCl), Vitamin B12 (as cyanocobalamin), Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium citrate carbonate), Iron (as ferrous succinate), Magnesium (as magnesium aspartate), Zinc (as zinc Krebs cycle chelates), Selenium (as L-selenomethionine), Chromium (as chromium polynicotinate), Dong Quai (Angelica sinensis) root extract, Licorice (Glycyrrhiza glabra) Root and Rhizome Extract, Milk Thistle (Silybum marianum) Fruit Extract, Black Cohosh (Cimicifuga racemosa) root extract, Chaste Tree (Vitex agnus-castus) berry extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/25/05

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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely

Michael P. Devereux Chief Financial Officer